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*Attorneys for Defendant  
Fresenius Kabi USA, LLC*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

NOVARTIS PHARMACEUTICALS  
CORPORATION et al.,  
Plaintiffs,

v.

WOCKHARDT USA LLC and WOCKHARDT  
LIMITED

and

SUN PHARMA GLOBAL FZE and  
SUN PHARMACEUTICAL INDUSTRIES  
LIMITED,

Defendants.

Civil Action No.: 12-3967(SDW)(MCA)

[Consolidated with Civil Action Nos.: 12-4393 and 13-1028 and 13-2379]

**ANSWER AND COUNTERCLAIMS  
OF DEFENDANT FRESENIUS  
KABI USA, LLC**

NOVARTIS PHARMACEUTICALS  
CORPORATION,

Plaintiff,

v.

ACTAVIS LLC, et al.

and

ACCORD HEALTHCARE INC.; FRESENIUS  
KABI USA, LLC; and HIKMA FARMACEUTICA  
S.A.,

Defendants.

Defendant Fresenius Kabi USA, LLC ("Fresenius") hereby answers the Complaint filed

by Plaintiff Novartis Pharmaceuticals Corporation (“Novartis” or Plaintiff”) and asserts counterclaims as follows:

**PRELIMINARY STATEMENT**

Plaintiff’s Complaint uses the term “Defendants” to refer, collectively, to Fresenius, Accord Healthcare Inc. (“Accord”), and Hikma Farmaceutica S.A (“Hikma”). Except as expressly set forth below, Fresenius has insufficient knowledge to admit or deny allegations regarding Defendants other than Fresenius, and therefore denies the same.

1. Paragraph 1 contains a description for which no answer is required.

**NATURE OF THE ACTION**

2. Fresenius admits that the Complaint purports to state an action that arises under the patent laws of the United States and the Declaratory Judgment Act. To the extent that paragraph 2 of the Complaint purports to characterize U.S. Patent No. 8,324,189 (the “‘189 Patent”), Fresenius states that the ‘189 Patent speaks for itself. To the extent that paragraph 2 of the Complaint states conclusions of law, no response is required from Fresenius. Fresenius denies the remaining allegations of paragraph 2 of the Complaint.

**THE PARTIES**

3. Upon information and belief, Fresenius admits that Plaintiff is a corporation organized under Delaware law with a principal place of business in East Hanover, New Jersey. Fresenius admits that the ‘189 patent on its face identifies Novartis Pharmaceuticals Corporation as an assignee. Fresenius is without information sufficient to admit or deny the remaining allegations in paragraph 3, and therefore denies the same.

4. Fresenius is without information sufficient to admit or deny the allegations in paragraph 4, and therefore denies the same.

5. Fresenius is without information sufficient to admit or deny the allegations in paragraph 5 of the Complaint, and therefore denies the same.

6. Fresenius is without information sufficient to admit or deny the allegations in paragraph 6 of the Complaint, and therefore denies the same.

7. Fresenius is without information sufficient to admit or deny the allegations in paragraph 7 of the Complaint, and therefore denies the same.

8. Fresenius admits that it is a Delaware limited liability company. Fresenius denies that its principal place of business is at 1501 East Woodfield Road, Suite 300 East Schaumburg, Illinois. Fresenius's principal place of business is at Three Corporate Drive, Lake Zurich, Illinois. Fresenius admits that it sells generic drug products in New Jersey. To the extent that paragraph 8 states conclusions of law, no response is required from Fresenius. Fresenius denies the remaining allegations in paragraph 8 of the Complaint.

9. Fresenius admits that it submitted ANDA No. 091516 to the FDA, seeking approval to market a Zoledronic Acid Injection (the "ANDA Product"). To the extent that the allegations of paragraph 9 of the Complaint go further or are inconsistent, they are denied

#### **JURISDICTION AND VENUE**

10. Fresenius admits that the Court has jurisdiction over the subject matter of this action. To the extent that the allegations of paragraph 10 of the Complaint go further or are inconsistent, they are denied.

11. For purposes of this action only, Fresenius admits that venue with respect to Fresenius is proper in this District.

12. Fresenius admits that it sells generic drug products in the State of New Jersey. To the extent that paragraph 12 or its subparagraphs state conclusions of law, no response is

required from Fresenius. To the extent that paragraph 12 or its subparagraphs state allegations regarding Defendant Accord, Defendant Hikma, or Novartis's place of domicile, Fresenius is without sufficient information to admit or deny the allegations, and therefore denies the same. Fresenius denies the remaining allegations in paragraph 12 and its subparagraphs.

#### **STATEMENT OF FACTS**

13. Fresenius admits that zoledronic acid is the active ingredient of Zometa and that Zometa is approved for the indications listed in the current FDA-approved labeling. Fresenius is without information sufficient to admit or deny the remainder of the allegations in paragraph 13 of the Complaint, and therefore denies the same.

14. Fresenius admits that Zometa may be administered intravenously as a 4 mg dose. Fresenius is without information sufficient to admit or deny the remainder of the allegations in paragraph 14 of the Complaint, and therefore denies the same.

15. Fresenius admits that the '189 patent is entitled "Use of zoledronate for the manufacture of a medicament for the treatment of bone metabolism diseases" and that the '189 patent on its face shows an issue date of December 4, 2012. Fresenius admits that what appears to be a true and correct copy of the '189 patent is attached as Exhibit 1 to the Complaint. To the extent that paragraph 15 states conclusions of law, no response is required from Fresenius. Fresenius is without information sufficient to admit or deny the remaining allegations in paragraph 15, and therefore denies the same.

16. Fresenius admits that the Orange Book lists the '189 patent for Zometa with a strength of Eq. 4 mg base / 5 mL. To the extent that paragraph 16 states conclusions of law, no response is required from Fresenius. Fresenius denies the remaining allegations in paragraph 16.

17. Fresenius admits that the FDA regulates the manufacture, sale and labeling of

prescription drugs in the United States. Fresenius states that FDA regulations and the Hatch-Waxman Act speak for themselves. To the extent that the allegations in paragraph 17 go further or are inconsistent, they are denied.

18. Fresenius states that FDA regulations and the Hatch-Waxman Act speak for themselves. To the extent that the allegations in paragraph 18 go further or are inconsistent, they are denied.

19. Fresenius states that FDA regulations and the Hatch-Waxman Act speak for themselves. To the extent that the allegations in paragraph 19 go further or are inconsistent, they are denied.

20. Fresenius is without information sufficient to admit or deny the allegations in paragraph 20 of the Complaint, and therefore denies the same.

21. Fresenius admits that it notified Novartis by letter on March 25, 2013 (the “Notice Letter”) that it had submitted ANDA No. 091516 to the FDA, related to its proposed Zoledronic Acid Injection 4 mg / 5 mL product. To the extent that the allegations in paragraph 21 go further or are inconsistent, they are denied.

22. Fresenius is without information sufficient to admit or deny the allegations in paragraph 22, and therefore denies the same.

23. Fresenius admits the allegations of paragraph 23 with respect to statements regarding Fresenius. Fresenius is without information sufficient to admit or deny the allegations in paragraph 23 regarding Defendant Accord and Defendant Hikma and therefore denies the same.

24. Fresenius is without information sufficient to admit or deny the allegations in paragraph 24 regarding Defendant Accord and Defendant Hikma and therefore denies the same.

Fresenius admits that the complaint in this case was filed before forty-five days had passed after Novartis's receipt of Fresenius's notice letter. Fresenius denies that Novartis is entitled to any relief, including a 30-month stay upon the approval of Fresenius's ANDA, as a result of the timing of the filing of Novartis's complaint.

**COUNT I (INFRINGEMENT OF THE '189 PATENT)**

25. Fresenius incorporates each of the preceding paragraphs 1 to 24 as if fully set forth herein.

26. Fresenius is without information sufficient to admit or deny the allegations in paragraph 26, and therefore denies the same.

27. Fresenius admits that it had knowledge of the '189 patent when it submitted ANDA 091516 to the FDA. Fresenius denies the remaining allegations of paragraph 27.

28. Fresenius is without information sufficient to admit or deny the allegations in paragraph 28 of the Complaint, and therefore denies the same.

29. Fresenius is without sufficient information to admit or deny the allegations in paragraph 29 as to Defendant Accord and Defendant Hikma, and therefore denies the same. Fresenius otherwise denies the allegations of paragraph 29.

30. Fresenius is without sufficient information to admit or deny the allegations in paragraph 30 as to Defendant Accord and Defendant Hikma, and therefore denies the same. Fresenius otherwise denies the allegations of paragraph 30.

31. Fresenius is without sufficient information to admit or deny the allegations in paragraph 31 as to Defendant Accord and Defendant Hikma, and therefore denies the same. Fresenius otherwise denies the allegations of paragraph 31.

32. To the extent that paragraph 32 states conclusions of law, no response is required

from Fresenius. Fresenius is without sufficient information to admit or deny the allegations in paragraph 32 as to Defendant Accord and Defendant Hikma, and therefore denies the same. Fresenius otherwise denies the allegations of paragraph 32.

**PRAYER FOR RELIEF**

33. Fresenius denies each and every allegation in the Complaint not expressly admitted above.
34. Fresenius denies that the Plaintiff is entitled to the judgment and relief prayed for in paragraphs 1 through 3 of the Prayer for Relief.

**AFFIRMATIVE DEFENSES**

**FIRST AFFIRMATIVE DEFENSE**

35. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius's ANDA product does not and will not infringe any valid and enforceable claim of the '189 patent.

**SECOND AFFIRMATIVE DEFENSE**

36. One or more claims of the '189 patent are invalid for failure to comply with the conditions of patentability set forth in 35 U.S.C. §§ 101 et seq., including 35 U.S.C. §§ 101, 102, 103, 112 and/or 116, and/or for obviousness-type double patenting.

37. Fresenius reserves the right to raise further additional defenses as may be available upon the facts to be developed and under applicable substantive law.

**COUNTERCLAIM FOR DECLARATORY JUDGMENT**

Fresenius, for its counterclaim against Plaintiff, alleges as follows

**PARTIES**

1. Upon information and belief, Plaintiff-counterdefendant Novartis is a corporation

organized under Delaware law with a principal place of business in East Hanover, New Jersey.

2. Defendant-counterclaimant Fresenius is a limited liability corporation organized and existing under the laws of Delaware, having a principal place of business at Three Corporate Drive, Lake Zurich, Illinois.

**JURISDICTION AND VENUE**

3. This is a counterclaim for declaratory judgment of invalidity and noninfringement of the '189 patent. This counterclaim arises under the patent laws of the United States, Title 35 of the United States Code, is asserted pursuant to 28 U.S.C. §§ 1338, 2201, and 2202, and is based upon an actual controversy existing between Fresenius and Plaintiff as to the alleged validity and infringement of the '189 patent.

4. This Court has jurisdiction over the subject matter of this counterclaim pursuant to 28 U.S.C. § 1338(a). In addition, Plaintiff has invoked jurisdiction in this Court by way of its Complaint.

5. Plaintiff has submitted to the venue in this Court.

**COUNT I**  
**(Non-Infringement of the '189 Patent)**

6. Fresenius incorporates the preceding Counterclaim paragraphs 1 to 5 as if fully set forth herein.

7. Plaintiff has alleged that Fresenius infringes the '189 patent. Fresenius denies that it infringes the '189 patent.

8. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius's ANDA product does not and will not infringe, directly or indirectly, any valid and enforceable claim of the '189 patent, either literally or under the doctrine of equivalents.

9. An actual and justiciable controversy exists between Fresenius and Plaintiff concerning the non-infringement of the '189 patent.

10. Fresenius is entitled to a declaratory judgment that the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius's ANDA product does not and will not infringe, directly or indirectly, any valid and enforceable claim of the '189 patent.

**COUNT II**  
**(Invalidity of the '189 Patent)**

11. Fresenius incorporates the preceding Counterclaim paragraphs 1 to 10 as if fully set forth herein.

12. One or more claims of the '189 patent is invalid for failure to comply with the conditions of patentability set forth in 35 U.S.C. §§ 101 et seq., including 35 U.S.C. §§ 101, 102, 103, 112 and/or 116, and/or for obviousness-type double patenting.

13. An actual and justiciable controversy exists between Fresenius and Plaintiff concerning the invalidity of the '189 patent.

14. Fresenius is entitled to a declaratory judgment that one or more claims of the '189 patent are invalid.

**PRAYER FOR RELIEF**

WHEREFORE, Fresenius respectfully requests this Court enter judgment in its favor against Plaintiff, granting the following relief:

A. An order dismissing Plaintiff's Complaint, in its entirety, with prejudice;

B. An order entering judgment in favor of Fresenius and against Plaintiff;

C. An order declaring any and all asserted claims of the '189 patent invalid and/or not infringed by Fresenius;

D. An order enjoining Plaintiff, its officers, agents, servant, employees, attorneys,

and representatives and any successors and assigns thereof, from charging or asserting infringement of any claim of the '189 patent against Fresenius, or anyone in privy with Fresenius;

E. An order awarding Fresenius its reasonable costs (including expert fees), expenses, and attorney's fees in this action, this being an exceptional case in accordance with 35 U.S.C. § 285, among other grounds; and

F. An order granting such other and further relief as this Court may deem just and proper.

Dated: June 19, 2013

**LITE DEPALMA GREENBERG, LLC**

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*Attorneys for Defendant  
Fresenius Kabi USA, LLC*

**LOCAL CIVIL RULE 11.2 CERTIFICATION**

Pursuant to Local Civil Rule 11.2, the undersigned counsel for Defendant Fresenius Kabi USA, LLC hereby certifies that this matter is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding, except *Novartis Pharmaceuticals Corporation, et al. v. Wockhardt USA LLC, et al.*, Civil Action No. 12-3967 (SDW)(MCA), *Novartis Pharmaceuticals Corporation, et al. v. Sun Pharma Global FZE, et al.*, Civil Action No. 12-4393 (SDW)(MCA), and *Novartis Pharmaceuticals Corporation v. Actavis LLC, et al.*, Civil Action No. 13-1028 (SDW)(MCA). The foregoing actions and this action have been consolidated by Order of this Court.

Dated: June 19, 2013

s/Michael E. Patunas  
Michael E. Patunas

**CERTIFICATE OF SERVICE**

I, Michael E. Patunas, hereby certify that on this day, I caused a copy of the Answer and Counterclaims of Defendant Fresenius Kabi USA, LLC to be served on all Counsel of Record through the Court's ECF system.

Dated: June 19, 2013

*s/Michael E. Patunas*  
Michael E. Patunas